March 30, 2009

EA-09-038
NMED No. 080296

E. Lynn McGuire, Director
National Health Physics Program (115 HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 030-34325/2008-029(DNMS), PHILADELPHIA, PENNSYLVANIA, VA MEDICAL CENTER

Dear Mr. McGuire:

This refers to the special inspection conducted on July 23-25 and September 9-12, 2008, with continued NRC in-office review through February 9, 2009, concerning the Department of Veterans Affairs (DVA), Master Materials License (MML), Medical Center, Philadelphia, Pennsylvania (permittee). The continued NRC in-office review included assessing your 15-day written reports, the NRC Medical Consultant's report received December 30, 2008, and review of dosimetry and audit data received on February 9, 2009. The purpose of the inspection was to review the facts, circumstances, root and contributing causes and proposed corrective actions regarding ninety-two reported medical events that occurred between February 2002 and June 5, 2008. The enclosed report presents the results of this inspection. The NRC also contracted a medical consultant, Ronald E. Goans, Ph.D., M.D., to review the medical significance of a selected number of these medical events. Dr. Goans' report is enclosed.

Based on the results of this inspection, six apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about--nrc/regulatory/enforcement/enforce-pol.html. The apparent violations involved the failure to: (1) develop adequate written procedures to provide high confidence that each prostate seed implant administration is in accordance with the written directive as required by Title 10 Code of Federal Regulation (CFR) 35.41(a)(2); (2) develop procedures that address methods for verifying that administration is in accordance with the treatment plan and written directive as required in 10 CFR 35.41(b)(2); (3) train supervised individuals regarding identification and reporting requirements for medical events as required in 10 CFR 35.27(a)(1); (4) instruct a non-supervised individual regarding identification and reporting of medical events as required in 10 CFR 19.12(a)(4); (5) record total dose on a written directive as required by 10 CFR 35.40(b); and (6) provide required information in several 15-day reports to the NRC as required in 10 CFR 35.3045(d). The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you and members of your staff at the preliminary inspection exit meeting on September 12, 2008, in Philadelphia, PA, and a subsequent teleconference exit meeting on

January 13, 2009. Our final exit meeting informing you of the apparent violations and scheduling the enforcement conference was conducted via teleconference on March 18, 2009.

Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued for these inspection findings at this time. In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review.

An open predecisional enforcement conference to discuss these apparent violations has been scheduled for April 29, 2009, at 1:00 p.m. (CDT) in the Region III office in Lisle, Illinois. This conference will be open to public observation in accordance with Section V of the NRC Enforcement Policy.

In addition to the apparent violations, the NRC identified several concerns that were contributing factors to the medical events. The concerns involve inadequate management oversight of the prostate brachytherapy program by the Radiation Safety Officer and the Radiation Safety Committee, in addition to an overall lack of a safety culture in which safety concerns went unreported.

As stated in the enclosed NRC Regulatory Issue Summary 2005-18, "Guidance for Establishing and Maintaining a Safety Conscious Work Environment," a strong safety culture is described as the "necessary full attention to safety matters." A strong safety culture is also described as having a "safety-first focus." Attributes include the safety-over-production principle, procedural adherence, and conservative decision-making. Therefore, in addition to discussing the apparent violations, you should also be prepared to discuss the specific actions that have been or will be taken to address the concerns identified in Section 4.2 of the enclosed NRC inspection report.

The decision to hold a predecisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. The NRC specifically wishes to ensure that we have a common understanding of the facts, the root causes, and reasons for the missed opportunities to identify the medical events. During this conference, we also request that you discuss the seriousness of the injuries to the patients, including, but not limited to: (1) the potential for continuing medical issues; (2) the potential increased risk of recurrence of cancer; and (3) the need for continuing patient follow up. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful.

You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations is required at this time.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be available electronically in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

We appreciate your cooperation and will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA/

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

Docket No. 030-34325
License No. 03-23853-01VA
Permit No. 37-00062-07

Enclosures:
1. Special Inspection Report 030-34325/2008-029 (DNMS)
2. Medical Consultant's Report
3. Excerpt from NRC Information Notice 96-28
4. NRC Regulatory Issue Summary 2005-18

cc w/encls: Richard Citron, Medical Center Director-VA Medical Center-Philadelphia
Mary Moore, Ph.D, Radiation Safety Officer-VA Medical Center-Philadelphia

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Letter to E. Lynn McGuire from Steven A. Reynolds dated March 30, 2009

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 030-34325/2008-029(DNMS), PHILADELPHIA, PENNSYLVANIA, VA MEDICAL CENTER

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REGION III

Docket No.:	030-34325
License No.:	03-23853-01VA
Report No.:	030-34325/2008-029(DNMS)
Licensee:	Department of Veterans Affairs (DVA)
Location Inspected:	Veteran Affairs Medical Center, Philadelphia, Pennsylvania [permittee under the DVA's Master Materials License]
Address:	3900 Woodland Ave. Philadelphia, PA 19104
Inspection Dates:	July 23-25, 2008, and September 9-12, 2008, with continued in-office review through February 9, 2009
Preliminary Exit Meeting:	September 12, 2008
Final Exit Meeting:	March 18, 2009
Inspectors:	Darrel G. Wiedeman, Senior Health Physicist Cassandra F. Frazier, Senior Health Physicist
Approved By:	Patricia J. Pelke, Chief Materials Licensing Branch Division of Nuclear Materials Safety

Enclosure 1

EXECUTIVE SUMMARY

Veterans Affairs Medical Center-Philadelphia

NRC Inspection Report No. 030-34325/08-29 (DNMS)

This special inspection was conducted to examine the facts, circumstances, root and contributing causes, and proposed corrective actions regarding 92 medical events that occurred between February 2002 and June 5, 2008, involving patients that received brachytherapy iodine-125 (I-125) seed prostate implants at the Veterans Affairs Medical Center, Philadelphia (PVAMC).

The Department of Veterans Affairs (DVA) holds a master materials license (MML), which authorizes the DVA to issue permits for the possession and use of licensed material, and ties the licensee to a framework of oversight consistent with NRC regulations and inspection and enforcement policies, procedures, and guidance. The DVA National Radiation Safety Committee (NRSC) has the responsibility for providing oversight of the DVA's implementation of its MML and associated permittee activities. The NRSC has delegated the authority to manage the DVA radiation safety program to its National Health Physics Program (NHPP). The licensee is the Department of Veterans Affairs (DVA). The PVAMC is a permittee under the DVA's MML.

On May 16, 2008, the NRC received a notification from the DVA (licensee) that a patient undergoing treatment on May 5, 2008, for prostate cancer at the PVAMC (permittee) received a dose to the prostate that was less than 80 percent of the prescribed dose. In accordance with Title 10 Code of Federal Regulations (CFR) 35.3045(a)(1), this represented a medical event. The NHPP performed a reactive inspection to review the circumstances of the May 2008 medical event and requested a review of an additional 10 to 20 prostate brachytherapy cases by the PVAMC. The review identified additional patients who received doses to the prostate that were less than 80 percent of the prescribed dose. Based on these results, the scope of the review was expanded to include all of the prostate brachytherapy treatments (116) performed since the inception of the prostate brachytherapy treatment program (February 2002).
In September 2008, PVAMC completed their evaluation and identified a total of 92 medical events that occurred between February 2002 and June 5, 2008. Thirty-five (35) medical events involved doses to an organ or tissue, other than the treatment site (prostate), that received doses above 0.50 Sieverts (Sv) and 50 percent more than the expected dose, and 57 medical events involved under doses to the prostate where the prostate received a dose that was less than 80 percent of the prescribed dose.

The NRC conducted a special inspection on July 23 through 25, 2008, and from September 9 through 12, 2008, of the PVAMC in response to the multiple medical events reported. The inspectors determined that a substantial programmatic breakdown of the prostate brachytherapy program occurred at the PVAMC due to the number and significance of the medical events. The inspectors identified six apparent violations and several concerns. The apparent violations involve the failure to: (1) develop adequate written procedures to provide high confidence that each prostate brachytherapy treatment administration is in accordance with the written directive; (2) develop procedures that address methods for verifying that the administration is in accordance with the treatment plan and written directive; (3) train supervised individuals regarding identification and reporting requirements for medical events; (4) instruct a non-supervised individual regarding identification and reporting requirements for medical

events; (5) record the total dose on a written directive; and (6) provide required information in several 15-day written reports to the NRC.

In addition to the apparent violations, the inspectors identified several concerns that were contributing factors to the medical events that involve inadequate management oversight of the prostate brachytherapy program and lack of a safety culture.

In response to the multiple medical events identified, the PVAMC Director appointed an Administrative Board of Investigation (ABI) to review the facts and circumstances surrounding the possibility that patients involved in the prostate brachytherapy program may have received doses to their prostates that were lower than the dose prescribed. The root cause of the medical events as reported in the ABI's report dated September 5, 2008, indicate that the permittee's contractors (physicians and physicists) accepted a substandard approach to brachytherapy treatments and allowed the system to fail when post implant dosimetry was performed, low doses were observed, yet no corrective action was taken. Five indirect root causes also contributed to the events: (1) there was a lack of safety culture; (2) there was a misperception that safety checks were performed by other team members, resulting in a succession of minor technical errors; (3) there was inadequate supervision by the physician authorized user; (4) there was inadequate program oversight and peer review of the brachytherapy program by the licensee; and (5) there was inadequate training of licensee staff. The NRC agrees with these root and contributory causes.

The permittee's corrective actions include: (1) revising procedures for the prostate brachytherapy treatments to include an evaluation and verification that the administered dose was in accordance with the written directive; (2) directions that require the radiation oncology staff to stop the procedure if there is any uncertainty associated with the treatment; (3) amending the PVAMC Sealed Source Radiotherapy policy to include: a) a comparison and evaluation of both treatment plans and associated calculations with the written directive; b) direction to allow prostate brachytherapy treatments to proceed only when the treatment planning computer is able to produce pre or post-treatment plans; and c) immediately reporting all deviations that exceed ten percent of the prescribed dose or dose fraction to the Radiation Safety Officer (RSO) and quality management staff; (4) institute a medical center peer-review system for radiation oncology services and post-treatment evaluations; (5) provide radiation safety training to radiation oncology staff, nuclear medicine staff, new employees, trainees and contractors regarding NRC regulations for written directives and medical events; (6) revise the contract for radiation oncology services to realign these services under the RSO; (7) institute an internal quality assurance program to ensure communications between radiation oncology team members regarding safety and treatment concerns; and (8) suspend prostate brachytherapy treatments until all the corrective actions have been completed and they have been approved to re-start by the NHPP.

The NRC contracted a medical consultant to review a selected number of the medical events and determine if any health consequences to the patients were expected. The consultant noted that the seed placement in the cases reviewed was quite erratic and not consistent with current medical standards. The consultant generally agreed with the PVAMC's dose estimates to the patients. However, the report stated that erratic seed placement caused a number of cases to have elevated doses to the rectum, bladder, or perineum. The consultant identified one specific patient with rectal bleeding where the increased dose to the patient's colon, resulting from erratic seed placement, could have been a contributing factor to the condition.

REPORT DETAILS

1 Program Scope and Inspection History

The Department of Veterans Affairs (DVA) holds a master materials license (MML), which authorizes the DVA to issue permits for the possession and use of licensed material, and ties the licensee to a framework of oversight consistent with NRC regulations and inspection and enforcement policies, procedures, and guidance. The DVA National Radiation Safety Committee (NRSC) has the responsibility for providing oversight of the DVA's implementation of its MML and associated permittee activities. The NRSC has delegated the authority to manage the DVA radiation safety program to its National Health Physics Program (NHPP). The licensee is the Department of Veterans Affairs (DVA). The Veterans Affairs Medical Center, Philadelphia (PVAMC) is a permittee under the DVA's MML.

The PVAMC is a medical broad scope permittee authorized by the MML to use a variety of byproduct materials for diagnostic and therapeutic purposes. The therapeutic treatments include brachytherapy iodine-125 (I-125) used for prostate implants.

The last NRC inspection of the PVAMC was on August 6, 2003, and no violations were identified. The previous NHPP inspection of the medical center was on January 23-24, 2008, and two non-cited violations were identified. In response to the medical event reported on May 16, 2008, that a patient undergoing treatment on May 5, 2008, for prostate cancer at the PVAMC (permittee) received a dose to the prostate that was less than 80 percent of the prescribed dose, the NHPP conducted reactive inspections on May 28-29, 2008, and June 24-25, 2008, with continuing review through October 3, 2008. They identified four violations that were categorized as a Severity Level III problem. The violations included the PVAMC's failure to: (1) have adequate written procedures to provide high confidence that each administration was in accordance with the written directive; (2) have adequate written procedures to address verification that the administration was in accordance with the treatment plan and written directive, and included checks of the computer-generated dose calculations; (3) document the required information on a written directive for a brachytherapy treatment; and 4) notify the NRC no later than the next calendar day after discovery of medical events.

Two potential medical events involving prostate brachytherapy treatments occurred in the past at the PVAMC. In two I-125 seed prostate implants performed on February 3, 2003, and October 3, 2005, respectively, a large fraction of the seeds were mistakenly implanted into the patients' bladders instead of their prostate glands. NRC conducted a reactive inspection following the February 3, 2003, event and, in a report dated June 30, 2003, concluded that the event did not constitute a medical event because the written directive had been revised by the physician in the operating room to indicate the actual number of seeds implanted. The patient (Patient A) received a second implant on March 31, 2003. The details of the second event (Patient B), were described by the NHPP in a letter to the NRC dated October 19, 2005, which stated that because the written directive had been revised by the physician in the operating room (to indicate the actual number of seeds implanted), the circumstances did not represent a medical event. Both of these events were included in the PVAMC's review of all prostate brachytherapy treatments performed since the inception of the program and

were subsequently determined to be medical events. Patient A received a dose that exceeded 0.50 Sv and 50 percent more than the expected dose to an organ or tissue (rectum), other than the treatment site (prostate) as a result of the two implant procedures. Patient B received an administered prostate dose that was less than 80 percent of the prescribed dose.

2 Chronology of Events and Licensee Investigation

2.1 Inspection Scope

The inspectors evaluated the facts and circumstances leading up to the reported medical events and the permittee's event investigation. The inspectors toured the facility; observed equipment used for the prostate brachytherapy treatments; interviewed selected individuals, including the authorized user physicians, contract medical physicists, the Radiation Safety Officer (RSO); and reviewed procedures and selected patient treatment records. The inspectors developed a chronology of events that led to the medical events.

2.2 Observations and Findings

On February 25, 2002, PVAMC initiated its prostate brachytherapy program and implanted its first patient. The PVAMC has performed 116 prostate brachytherapy treatments since the inception of the program. The prostate brachytherapy program is maintained by contracted physicians and medical physicists to provide radiation therapy services.

On February 3, 2003, during an I-125 seed prostate implant, many seeds (40 out of 74) were mistakenly implanted into the patient's bladder and subsequently recovered. The NRC conducted a reactive inspection for the event and, in a report dated June 30, 2003, concluded that the insertion of seeds into the bladder and subsequent removal of the seeds did not constitute a medical event, because the written directive was revised by the authorized user physician in the operating room to indicate the actual number of seeds implanted into the patient. The patient received a second implant on March 31, 2003.

On October 3, 2005, during an I-125 seed prostate implant, many seeds (45 out of 90) were again mistakenly implanted into the patient's bladder and subsequently recovered. The NHPP conducted a reactive inspection for the event (accompanied by an NRC inspector). The details of the event were described by the NHPP in a letter to the NRC dated October 19, 2005, which stated that because the written directive had been revised by the physician in the operating room (to indicate the actual number of seeds implanted), the circumstances did not represent a medical event.

During the period of November/ December 2006, the PVAMC experienced technical problems that prevented transfer of computerized tomography (CT) images to the VariSeed® treatment planning system. Post-treatment plans to evaluate prostate brachytherapy treatments were not possible using the VariSeed® treatment planning system. In November 2007, the technical problems preventing image transfer to the VariSeed® treatment planning system were resolved. However, post-treatment plans were not performed until December 2007 or later.

On April 18, 2008, an authorized user physician performed a trans-rectal ultrasound (TRUS) study on a patient for use in creating a prostate brachytherapy treatment plan. On April 25, 2008, a medical physicist created a treatment plan for the patient using the VariSeed® treatment planning system. The treatment plan, including the needle loading diagrams, called for I-125 seeds with an activity of 0.509 millicuries (mCi) per seed. The authorized user physician prepared a written directive that specified a prescribed dose of 160 gray (Gy) (equivalent to 160 Sieverts (Sv)) and I-125 seed activity of 0.380 mCi/seed. The written directive form in use at the time had a default activity of 0.380 mCi/seed. The authorized user physician reviewed the treatment plan for the patient, but did not identify the discrepancy in seed activity identified on the treatment plan (0.509 mCi/seed) and the written directive (0.380 mCi/seed). The authorized user physician approved and signed the written directive.

On April 29, 2008, a radiation safety staff member ordered I-125 seeds from the vendor. The order specified a seed activity of 0.380 mCi/seed and included a copy of the written directive (specifying seed activity of 0.380 mCi/seed) and the needle loading diagrams (which specified seed activity of 0.509 mCi/seed).

On May 1, 2008, the medical center received the seeds with an activity of 0.380 mCi/seed from the vendor. A radiation safety staff member performed a package receipt survey, but failed to identify that there was a discrepancy in seed activity identified on the written directive and on the treatment plan and needle loading diagrams.

On May 2, 2008, a medical physicist verified the activity of one seed from the package, but failed to realize that there was a discrepancy in the seed activity specified on the written directive and the seed activity specified on the treatment plan and needle loading diagrams.

On May 5, 2008, the prostate implant was performed by an authorized user physician who was assisted by an urologist and urology resident.

On May 12, 2008, a radiation safety staff member determined that the activity of the implanted seeds did not match the activity on the treatment plan and seed loading diagrams. The RSO was notified, who in turn informed the NHPP of the error in seed activity, but indicated that the error in seed activity was not considered to be a medical event because the projected D90 (dose received by at least 90 percent of the prostate volume) would be within 80 percent of the prescribed dose of 160 Gy (equivalent to 160 Sv) on the written directive. On May 14, 2008, the authorized user physician notified the patient about the error associated with seed activity.

On May 15, 2008, a medical physicist created a post-treatment plan using the VariSeed® computer treatment planning system. The post-treatment plan results indicated the D90 was 47 percent of the prescribed dose. NHPP notified the NRC Operations Center on May 16, 2008, of a possible medical event.

On May 28-29, 2008, the NHPP initiated an onsite reactive inspection at the PVAMC in response to the reported medical event. The NHPP requested that the permittee review

additional prostate implant cases (10-20) to determine whether the seed activity error was an isolated incident.

On June 11, 2008, the PVAMC Director suspended the prostate brachytherapy program. By this date, the expanded review of completed prostate treatments indicated that D90 doses to the prostate for 45 patients were 20 percent or more lower than the prescribed dose. Fourteen (14) of these patients received D90's that were 20 to 30 percent lower than the prescribed dose and 31 patients received D90's that were more than 30 percent lower than the prescribed dose.

On June 11, 2008, the PVAMC commissioned an external review of the entire prostate brachytherapy program to include all of the prostate brachytherapy treatments (116) performed since the inception of the program (February 2002). The external review included obtaining new CT images from patients and follow-up dosimetry to assess prostate doses.

On June 24-25, 2008, the NHPP conducted a reactive inspection at the PVAMC, with continued review through October 3, 2008.

On July 17, 2008, the PVAMC appointed an Administrative Board of Investigation (ABI) to "review the facts and circumstances surrounding the possibility that patients involved in the brachytherapy program may have received radiation doses of lower than prescribed strength to their prostate."

On September 5, 2008, the ABI issued a report and identified findings, root causes, and recommendations. The root cause of the medical events documented in the ABI's report indicated that contractors (physicians and physicists) accepted a substandard approach to brachytherapy treatments and allowed the system to fail when post implant dosimetry was performed, low doses were observed, yet no corrective action was taken. Five indirect root causes also contributed to the events: (1) there was a lack of safety culture; (2) there was a misperception that safety checks were performed by other team members, resulting in a succession of minor technical errors; (3) there was inadequate supervision by the physician authorized user; (4) there was inadequate program oversight and peer review of the brachytherapy program by the permittee and (5) there was inadequate training of permittee staff.

As of October 2, 2008, the licensee identified and reported to the NRC Operations Center (in Event Notification Report Number 44219), a total 92 of medical events for I-125 prostate brachytherapy implants that occurred between February 2002 and June 5, 2008. Of the 92 medical events reported, 35 involved doses that exceeded 0.50 Sv and 50 percent more than the expected dose to an organ or tissue, other than the treatment site (prostate), and 57 involved under doses to the prostate where the prostate received a dose that was less than 80 percent of the prescribed dose. The reported events included two previously reported and retracted events from February 3, 2003, (Patient A) and October 3, 2005, (Patient B). Based on the results of the external review conducted for these patients, it was determined that Patient A received a dose that exceeded 0.50 Sv and 50 percent more than the expected dose to an organ or tissue (rectum) as a result of undergoing two implant procedures. Patient B received an administered prostate dose that was less than 80 percent of the prescribed dose.

On October 16, 2008, the NHPP issued an inspection report and identified four violations, which were characterized as a Severity Level III problem. Based on the inspection, the NHPP determined that the permittee failed to: (1) have adequate written procedures to provide high confidence that each administration was in accordance with the written directive; (2) have adequate written procedures to address verification that the administration was in accordance with the treatment plan and written directive, and included checks of the computer-generated dose calculations; (3) document the required information on a written directive for a prostate brachytherapy treatment; and 4) notify the NRC no later than the next calendar day after discovery of medical events.

On November 21, 2008, the PVAMC provided a written response to the NHPP inspection report that contained erroneous information regarding training and did not concur with, or accept the inspection findings.

On December 29, 2008, the PVAMC provided a second written response to the NHPP inspection report and requested that their response dated November 21, 2008, be rescinded. The PVAMC accepted the inspection report findings, observations, and violations as cited in the report. They made commitments to focus on a safety culture, to increase management oversight, and to avoid undue reliance on affiliates or outside consultants.

2.3 Conclusions

Based on an initial assessment in response to a medical event reported on May 16, 2008, an external review of the entire prostate brachytherapy program was conducted to include all of the prostate brachytherapy treatments (116) performed since the inception of the program (February 2002). From May 16 to October 2, 2008, the licensee identified 92 medical events involving I-125 prostate brachytherapy implants that occurred between February 2002 and June 5, 2008. Of the 92 medical events reported, 35 involved doses above 0.50 Sv and 50 percent more than the expected dose to an organ or tissue, other than the treatment site (prostate), and 57 involved under doses to the prostate where the prostate received a dose that was less than 80 percent of the prescribed dose.

3 Scope and Methodology for Reporting Medical Events

3.1 Scope

The inspectors interviewed selected licensee staff, including the RSO, authorized user physicians, and medical physicists, and reviewed the methodology used by the permittee to evaluate prostate doses and identify medical events.

3.2 Observations and Findings

From the inception of the prostate brachytherapy program in February 2002 until June 5, 2008, 116 prostate brachytherapy treatments were performed on 114 patients. Two patients received a second prostate brachytherapy treatment, which resulted in 116 treatments. Two of the 114 patients treated died. The PVAMC confirmed that the deaths were unrelated to the prostate brachytherapy treatments the patients received.

Based on this information, the permittee's prostate brachytherapy program review included 114 brachytherapy treatments performed on 112 patients (the deceased patients and their brachytherapy treatments were not included in the review).

The PVAMC prostate brachytherapy program consisted of two authorized user physicians who prepared the written directives with a prescribed prostate dose of 160 Gy (equivalent to 160 Sv). The procedure involved seeds containing either 0.380 mCi or 0.509 mCi of I-125, based on the written directive prepared by the authorized user physician. Prior to each prostate implant, a pre-treatment plan was developed by the medical physicist and approved by the authorized user physician based on the specifications in the written directive. After the implant procedure, typically the following day, a post-treatment plan was developed based on a CT image interfaced with the VariSeed® treatment planning system. The results of the post-treatment plan were compared with the pre-treatment plan to verify that the administered dose was in accordance with the prescribed dose specified in the written directive.

The PVAMC used a two phase approach to determine whether or not prostate brachytherapy implants resulted in medical events as defined in 10 CFR Part 35.3045. The records for 114 prostate brachytherapy treatments for 112 patients were reviewed. Phase I consisted of evaluating prostate brachytherapy implants to assess whether the medical events reported involved under doses to the prostate (prostate received a dose that was less than 80 percent of the prescribed dose as defined in 10 CFR Part 35.3045(a)(1)(i)). The evaluation required that a new post-treatment plan be generated for each case and compared with the initial pre-treatment plan to determine whether the administered dose was in accordance with the written directive. Patients with post-treatment plans in which the calculated D90 dose to the prostate was less than 80 percent of the prescribed dose were required to obtain a recent CT scan. An independent radiation oncology physician re-contoured the prostate from the recent CT scan. The new post-treatment plans were prepared by an independent medical physicist and the D90 dose was re-calculated. Based on the new post-treatment plans and D90 doses generated for these patients, the PVAMC determined that 57 medical events occurred that involved under doses to the prostate (prostate received a dose that was less than 80 percent of the prescribed dose on the written directive).

Phase II consisted of evaluating the prostate brachytherapy treatments to assess whether the medical events involved doses above 0.50 Sv and 50 percent more than the expected dose to an organ or tissue, other than the treatment site (prostate), as defined in 10 CFR Part 35.3045(a)(3). The evaluation involved a review of the initial post-treatment plans, by an independent radiation oncology physician, in which the D90 prostate doses were greater than 80 percent of the prescribed dose. The independent radiation oncology physician made an assessment to determine whether or not the contours from the original post-treatment plans should be revised and subsequently determined, on a case-by case basis, that a recent CT scan should be obtained. The new CT scans were contoured by the independent radiation oncology physician and the D90 doses to the prostate were re-calculated by an independent medical physicist, and doses to the bladder and rectum were also included. The D90 doses were also re-calculated for the original post-treatment CT scans (with acceptable original contours) by the independent radiation oncology physician.

The PVAMC established the following criteria to identify doses to organs or tissues other than the prostate: (1) Rectum - dose to 1.33 cc (cubic centimeter) volume exceeded 150 percent of the pre-treatment plan dose; (2) External tissue including the perineum - 5 or more seeds located beyond 1 centimeter (cm) exterior, and inferior, to the surface of the prostate; and (3) Bladder - 3 or more seeds located in the bladder wall. The basis for the criteria included:

(a) Rectum -The D1.33 (dose to 1.33 cc) was selected because it is the volume the VariSeed® treatment planning program used to indentify high dose volume during the pre-treatment planning. The D1.33 is also found in the literature: "Defining the Risk of Developing Grade 2 Proctitis Following 1-125 Prostate Brachytherapy using a Rectal Dose-Volume Histogram Analysis."

(b) Tissue External to Prostate - A perimeter of 1 cm was selected because it fully encompassed seeds positioned parallel and perpendicular to the external prostate surface. It was determined that any prostate brachytherapy seed protruding beyond the 1 cm cloud around the prostate was counted as exterior to the prostate and evaluated for dose contribution to the perineum, rectum and bladder.

(c) Tissue Inferior to Prostate - A determination was made that 10 percent (5) of the minimum number (53) of seeds implanted in the Phase II patients located more than 1 cm exterior to and inferior to the surface of the prostate was the criteria for a possible medical event.

(d) Bladder - The criteria of 3 or more seeds located in the bladder wall was selected based on the review of a patient's post-treatment plan which identified that 2 seeds in the bladder contributed to less than 60 Gy (equivalent to 60 Sv) to the bladder wall. The dose to the bladder wall with the seeds in the wall was compared to the dose to the bladder wall with the seeds removed. This criteria was well below the bladder tolerance dose.

Based on the criteria stated above, the PVAMC determined that 35 medical events occurred that involved doses above 0.50 Sv and 50 percent more than the expected dose to an organ or tissue, other than the treatment site (prostate), and 57 medical events occurred that involved under doses to the prostate (prostate received a dose that was less than 80 percent of the prescribed dose).

3.3 Conclusion

The inspectors determined that the scope, methodology, and criteria used for assessing medical events appeared consistent with current industry standards and practice.

4 Procedures for Brachytherapy Treatments

4.1 Inspection Scope

The inspectors reviewed selected brachytherapy program procedures specific to permanent I-125 prostate brachytherapy seed implants. The inspectors interviewed the RSO, the authorized user physicians, and the medical physicists.

4.2 Observations and Findings

The PVAMC indicated that it was their standard practice to use CT images of the treatment site taken the day after the implant, and use the images to confirm the number of seeds implanted in the prostate and develop a final radiation dosimetry plan based on the actual distribution of the seeds. The final radiation dosimetry plan would serve as a record of the treatment and be compared to the pre-treatment plan and written directive.

Title 10 CFR 35.41(a) states, in part, that, for any administrations requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

The inspectors determined that between December 2006 and November 2007, the permittee used the CT images to confirm the number of seeds implanted, but did not develop a final post-treatment plan based on the actual distribution of the implanted seeds because of computer interface problems associated with their VariSeed® treatment planning system and the CT images. The permittee continued to treat patients during this period even though they were not capable of determining that the administered dose was in accordance with the written directive and pre-treatment plan. While the CT images could provide information on the number and distribution of the seeds in the prostate, they did not provide sufficient information to determine the dose to the prostate. The procedures did not provide high confidence that each administration was in accordance with the written directive.

During this same period, post-treatment dose verifications were not performed on sixteen patients due to computer interface problems. Furthermore, after the interface problems with the computer system were resolved in November 2007, seven additional post-treatment plans were not completed for seven patients who received prostate brachytherapy implants in December 2007. Specifically, CT images were not interfaced with the VariSeed® treatment planning computer to verify that the dose to the treatment site was in accordance with the written directive.

The permittee's procedure entitled "Procedure 00-76, Sealed Source Radiotherapy," dated November 2005, and the previous version dated November 2002, did not require that the dose to the treatment site be verified to ensure that the administered dose was in accordance with the written directive. The inspectors determined that 92 prostate brachytherapy treatments were administered between February 2002 and June 2008, and the administered dose was not in accordance with the written directive. Specifically, 83 prostate brachytherapy treatments were administered between March 17, 2003, (date that the MML was issued) to June 5, 2008, and the administered dose was not in accordance with the written directive. Additionally, between February 2002 to

March 17, 2003, (prior to the MML), nine prostate brachytherapy treatments were administered and the dose was not in accordance with the written directive. The licensee's failure to develop and implement adequate procedures to provide high confidence that the prostate implant was performed in accordance with the written directive is an apparent violation of 10 CFR 35.41(a)(2).

Title 10 CFR 35.41(b), requires, in part, that the procedures required by 10 CFR 35.41(a) must address methods for verifying that the administration of byproduct material is in accordance with the treatment plan, if applicable, and the written directive.

The PVAMC's procedures entitled, "Procedure 00-76, Sealed Source Radiotherapy," dated November 2005, and November 2002, states that radiation therapy will receive the sources from the RSO, and verify that the number of seeds and radioactivity received is correct for the treatment. The PVAMC's procedures did not describe the methods used to determine how the number of seeds and radioactivity received are verified to ensure that it is correct for the treatment. Specifically, for a prostate brachytherapy treatment performed on May 5, 2008, the radiation therapy staff failed to verify that the radioactive sources received were correct for the treatment. The licensee's failure to develop procedures to verify that the administration of byproduct material is in accordance with the treatment plan, if applicable, and the written directive is an apparent violation of 10 CFR 35.41(b)(2).

Title 10 CFR 35.40 (b) states that the written directive for manual brachytherapy must specify, after implantation but before completion of the procedure, "the radionuclide, treatment site, number of sources, and total source strength and exposure time (or total dose)." The NRC inspectors identified a written directive dated April 25, 2008, (date of implant May 5, 2008,) that did not have the number of sources, or total dose recorded on the written directive. The PVAMC's failure to record number of sources and total dose after implantation, but before completion of the procedure, on the written directive is an apparent violation of 10 CFR 35.40 (b)(6).

In addition to the apparent violations, the NRC inspectors identified four concerns involving the PVAMC's prostate brachytherapy program. These concerns are: (1) 2007 quarterly radiation staff audits consistently indicated that written directives were in full compliance with the requirements, yet during the same period the permittee experienced computer interface problems associated with their VariSeed® treatment planning computer and CT images. The PVAMC continued to treat patients during this period even though they were not capable of determining that the administered dose was in accordance with the written directive and pre-treatment plan. Additionally, the 4th quarter 2006 radiation staff audit indicated that there was a problem with the computer interface systems. However, during the next quarter (March 2007) Radiation Safety Committee (RSC) meeting, there was no discussion of the computer interface problem; (2) the RSO reported to the RSC in September 2007 and again in December 2007, that post plans for prostate brachytherapy had not been completed due to the continuing image transfer problems associated with the CT scans and the VariSeed® treatment planning system. The RSC assigned no "action item" to resolve the issue and the RSC was aware that there was a three month backlog of prostate post plans and took no action to correct this issue. After the problem was resolved in November 2007, the prostate post-treatment plans used to determine the dose delivered to the patient were not being performed; (3) annual audits of the radiation safety

program that had been performed by the RSO were not finalized and provided to the RSC for review. In addition, there is no indication that the RSC requested the audits to review; and (4) the PVAMC lacked a safety culture for reporting radiation concerns to the appropriate individuals. As an example, interviews of two medical physicists indicated that they had concerns about a physician they worked with under dosing patients. One physicist indicated that he raised a concern to the authorized user physician in 2002 and no action was taken by the physician. The physicist did not raise the concern with the radiation safety staff. The other physicist raised his concern to a physician at an affiliate institution that provided contracted radiation oncology services to the PVAMC, but never raised the concern with the PVAMC's radiation safety staff or management.

4.3 Conclusions

The inspectors identified apparent violations of 10 CFR 35.41(a)(2) concerning the licensee's failure to develop adequate procedures to provide high confidence that prostate brachytherapy treatments were performed in accordance with the written directive; and 10 CFR 35.41 (b)(2), for failure to address the methods used to verify that the administered dose is in accordance with the treatment plan and written directive.

The inspectors also identified an apparent violation of 10 CFR 35.40(b)(6) that involved the licensee's failure to record the number of sources and total dose on a written directive dated April 25, 2008, for an implant performed on May 5, 2008.

In addition to the apparent violations, the inspectors identified concerns that were contributing factors to the medical events that include: (1) inadequate quarterly audits of the brachytherapy program by the radiation safety staff; (2) failure of the RSC to take action regarding computer interface problems; (3) annual audits of the radiation safety program conducted by the RSO for 2006 and 2007 were not finalized; and (4) lack of a safety culture.

5 Training

5.1 Inspection Scope

The inspectors interviewed the RSO, authorized user physicians and medical physicists to determine the extent of their knowledge and training regarding identification and reporting requirements for medical events and reviewed training records.

5.2 Observations and Findings

During interviews of two medical physicists (supervised individuals), both stated that they were never instructed on the requirements for identifying and reporting requirements for a medical event by the PVAMC. During the interview, the authorized user physician stated that he was never instructed on the NRC requirements for identifying and reporting medical events by the PVAMC. In addition, the PVAMC did not provide records of any training they had provided to the supervised individuals and authorized user physician.

Title 10 CFR 35.27(a)(1) requires that in addition to the requirements in 10 CFR 19.12, the licensee must instruct the supervised individual in the licensee's written radiation

protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material.

The permittee's failure to instruct two medical physicists (supervised individuals) regarding the requirements for identifying and reporting medical events is an apparent violation of 10 CFR 35.27(a)(1).

Title 10 CFR 19.12(a)(4) requires that all individuals, who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem, shall be instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses.

The permittee's failure to provide training regarding identification and reporting requirements for medical events to an authorized user physician that received a dose in excess of 100 mrem in a year is an apparent violation of 10 CFR 19.12(a)(4).

5.3 Conclusions

The inspectors identified two apparent violations regarding training; an apparent violation of 10 CFR 35.27(a)(1) for failure to provide training to two medical physicists (supervised individuals) and an apparent violation of 10 CFR 19.12(a)(4) was identified for failure to provide training to one authorized user physician.

6 Notifications and Reports

6.1 Inspection Scope

The inspectors interviewed the RSO, authorized user physicians, medical physicists, and radiation oncology staff to determine what event notifications had been made. The inspectors also reviewed the event notifications to the NRC Operations Center on May 16, 2008, (Event No. 44219) including subsequent updates, and the 15 day written reports submitted to the NRC dated June 21; July 8, 15, 21, 22, 30, and 31; and August 4 and 7, 2008.

6.2 Observations and Findings

From May 16 to October 2, 2008, 92 medical events were identified that involved I-125 prostate brachytherapy implants that occurred between February 2002 and June 5, 2008. The radiation oncology staff notified all 92 patients involved in the medical events. The referring physicians were also notified. Title 10 CFR 35.3045(3)(d)(iv)(v) and (vi) requires a 15-day written report to the NRC. The written report must include: (1) why the event occurred; (2) the effect, if any, on the individuals; and (3) what actions, if any, have been taken or planned to prevent recurrence.

The inspectors identified that several of the 15-day reports were missing the required information. As an example, reports dated June 21; July 8, 15, 21, 22, 30, and 31; and August 4 and 7, 2008, did not include information describing: (1) why the event occurred; (2) the effect on the individuals, and (3) what actions, if any, had been taken to prevent recurrence. The licensee's failure to include the required information in their 15-day reports is an apparent violation of 10 CFR 35.3045(d)(1) (iv) (v) and (vi).

Title 10 CFR 35.3045(c) requires licensees to notify the NRC Operations Center, by telephone, no later than the next calendar day after discovery of a medical event. The NRC is reviewing the applicability of 10 CFR 35.3045(c) notification requirements as it relates to the 92 reported medical events as an Open Item. The findings associated with the NRC's review of the Open Item will be documented in separate correspondence.

6.3 Conclusions

The inspectors identified an apparent violation associated with the failure to provide the required information in several 15-day written reports as required by 10 CFR 35.3045(d)(1) (iv) (v) and (vi). The inspectors identified one Open Item regarding the notification requirements in 10 CFR 35.3045(c). The findings associated with the NRC's review of the Open Item will be documented in separate correspondence.

7 Licensee Corrective Actions

7.1 Inspection Scope

The inspectors interviewed selected licensee personnel concerning their proposed corrective actions. The inspectors also reviewed the corrective actions described in the ABI report dated September 5, 2008, corrective actions identified in the NHPP's inspection report dated October 16, 2008, and the corrective actions identified in the PVAMC's response dated December 29, 2008.

7.2 Observations and Findings

The inspectors determined that the NHPP initiated several immediate and long-term corrective actions to prevent recurrence of a similar event. As an "immediate" corrective action, the PVAMC suspended the prostate brachytherapy program on June 11, 2008, and ordered an external review by the ABI of the prostate brachytherapy program at PVAMC. The corrective actions included: (1) revising procedures for the prostate brachytherapy treatments to require that a post-treatment plan be performed the following day after surgery and 30-days later, and that the post-treatment plan include an evaluation and verification that the administered dose was in accordance with the written directive; (2) stopping the treatment if there was any uncertainty associated with the procedure; (3) amending the PVAMC Sealed Source Radiotherapy policy to include: a) a comparison and evaluation of both treatment plans and associated calculations with the written directive; b) direction to allow prostate brachytherapy treatments to proceed only when the treatment planning computer is able to produce pre or post-treatment plans; and c) immediately reporting all deviations that exceed ten percent of the prescribed dose or dose fraction to the RSO and quality management staff; (4) instituting a medical center peer-review system for radiation oncology services and post-treatment evaluations; (5) providing radiation safety training to radiation oncology staff, nuclear medicine staff, new employees, trainees and contractors regarding NRC regulations for written directives and medical events, including training on PVAMC's open door policy for reporting concerns and suspected violations; (6) revising the contract with affiliates providing radiation oncology services to realign those services under the RSO at the PVAMC; (7) instituting an internal quality assurance program to ensure communications

between radiation oncology team members regarding safety and treatment concerns; and (8) stopping any further prostate brachytherapy treatments until all of the corrective actions have been completed and they have been approved to re-start by the NHPP.

An additional corrective action included an external review by physicians and medical physics consultants who were experts in performing prostate brachytherapy treatments to evaluate the former prostate implant program and current program, and to incorporate their recommendations into hospital policies and procedures.

7.3 Conclusions

The inspectors determined that the licensee's proposed corrective actions were adequate to prevent recurrence of the medical events and the apparent violations.

8 NRC Medical Consultant's Review

8.1 Inspection Scope

The inspectors reviewed the medical consultant's written report to determine if any health consequences occurred as a result of the 92 medical events reported.

8.2 Observations and Findings

The NRC contracted a medical consultant, Ronald E. Goans, Ph.D., M.D., to review a selected number of the medical events and determine if any health consequences to the patients were expected. The consultant reviewed a total of 24 cases (14 cases where the prostate received less than 80 percent of the prescribed dose and 10 cases where the doses were above 0.50 Sv and 50 percent more than the expected doses to an organ or tissue, other than the treatment site (prostate)). The consultant's report noted that the seed placement in the cases reviewed was quite erratic and not consistent with current medical standards. The consultant generally agreed with the PVAMC's dose estimates to the patients. However, the report stated that erratic seed placement caused a number of cases to have elevated doses to the rectum, bladder, or perineum. The consultant identified one specific patient with rectal bleeding where the increased dose to the patient's colon, resulting from erratic seed placement, could have been a contributing factor to the condition.

8.3 Conclusions

The consultant generally agreed with the PVAMC's dose estimates to the patients. However, erratic seed placement caused a number of cases to have elevated doses to the patient's rectum, bladder, or perineum. The consultant identified one specific patient with rectal bleeding where the increased dose to the patient's colon, resulting from erratic seed placement, could have been a contributing factor to the condition. In addition, a directed biopsy of the patient's colon mucosa indicated an inflammatory condition (very likely ulcerative colitis).

9 Root Cause

9.1 Inspection Scope

The inspectors interviewed selected licensee personnel concerning the licensee's investigation into the causes that led to the medical events and reviewed the results and conclusions of the PVAMC's ABI report.

9.2 Observations and Findings

The root cause of the medical events documented in the ABI's report dated September 5, 2008, indicated that contractors (physicians and physicists) accepted a substandard approach to brachytherapy treatments and allowed "the system to fail when post implant dosimetry was performed, low doses were observed, yet no corrective action was taken" and the medical center "failed to take advantage of several opportunities for program reviews relating to the prostate brachytherapy program." Two indirect root causes also contributed to the events. First, there was a lack of safety culture, which included: (a) the medical physicist decision not to present the low D90 data to the authorized user physician; (b) the succession of minor technical errors which stemmed from a misperception that safety checks were performed by other team members; and (c) the authorized user physicians' belief that since the patients were not having complications, the implant quality must be acceptable. Additionally, the medical center failed to perform: (a) direct reviews of the program by the Chief of Radiation Therapy; (b) statistical reviews of the program by radiation safety; and (c) quality management reviews of the program. The ABI report further stated that these root causes contributed to a pattern of poor prostate brachytherapy treatments and the lack of program oversight allowed the trend of low D90 prostate brachytherapy treatments to continue.

The NHPP identified additional root causes for the medical events that included: (1) a failure to provide training to the authorized user physician, medical physicists, and Chief of Radiation Oncology Services, in the definition of a medical event and reporting requirements for a medical event; (2) inadequate written prostate brachytherapy procedures that lacked specificity about the roles and responsibilities to evaluate possible medical events; (3) inadequate preparation and ongoing clinical supervision to ensure appropriate seed distribution by the authorized user physicians; (4) inadequate evaluation of prostate brachytherapy treatments to identify the tasks in which a single human error might result in a significant treatment error; and (5) the physician authorized user and medical physicist (primary responsibility for preparing treatment plans and written directives), had limited experience in prostate brachytherapy procedures, and were not provide any retraining or briefing before patient treatments.

The NHPP identified additional contributing causes involving: (1) the failure to perform and evaluate post-treatment plans on patients from December 2006 through November 2007, due to computer interface problems; (2) inadequate supervision of the authorized user physician; and (3) inadequate program oversight of the prostate brachytherapy program by the permittee.

9.3 Conclusions

The inspectors agree with the conclusions regarding the root and contributing causes that led to the medical events.

10 Exit Meeting

The inspectors discussed the conclusions described in this report with the licensee during a preliminary exit meeting conducted at the licensee's facility on September 12, 2008, and a subsequent teleconference on January 13, 2009. The final exit meeting was conducted by telephone on March 18, 2009. The licensee did not identify any information reviewed during this inspection as proprietary in nature.

ATTACHMENT: SUPPLEMENTAL INFORMATION

SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

#•* Richard Citron, Director, VA Philadelphia
Martin Heyworth, M.D. Chief of Staff, VA Philadelphia
#•* Joel Maslow, M.D., Ph.D, Chairman, RSC, VA Philadelphia
#•* Linda Aumiller, Director, Quality Management, VA Philadelphia
#* Phyllis Rego, Executive Assistant, Director, VA Philadelphia
#* Al Sipple, Executive Assistant, Chief of Staff, VA Philadelphia
#* Steven Gallerizzo, Associate Director, Administration, VA Philadelphia
#•* Mary Moore, Radiation Safety Officer, VA Philadelphia
#• Paul Yurko, Program Manager, NHPP
#•* Gary Williams, Program Manager, NHPP

•* Charles M. Anderson, M.D., Ph.D., VA Central Office, NRSC, Chair
• Michael Morelamd, VISN 4 Director
* Barbara L. Forsha, Quality Management Officer, VISN 4
• Janelle Altman, Administrative Officer for Quality Management
•* Margaret O'Shea Caplan, Associate Director, Finance, VA Philadelphia
• M. Jain, M.D., Acting Chief of Staff
* Pratap Yagnick, M.D., Acting Chief of Staff, VA Philadelphia
• S. Yagnik, M.D., Associate Director, Administration
* Amit Maity, M.D., Ph.D., Chief, Radiation Oncology Service, VA Philadelphia
•* E. Lynn McGuire, Director, NHPP
•* Edwin Leidholdt, Ph.D, Program Manager, NHPP
* Thomas Huston, Program Manager, NHPP

Participated in onsite exit meeting on September 12, 2008
• Contacted by telephone on January 13, 2009, for exit meeting
* Contacted by telephone on March 18, 2009, for final exit meeting

LIST OF ACRONYMS USED

ABI	Administrative Board of Investigation
CFR	Code of Federal Regulations
cc	cubic centimeter
cm	centimeter
CT	Computerized Tomography
DVA	Department of Veterans Affairs
Gy	Gray
mCi	millicurie
MML	Master Materials License
NHPP	National Health Physics Program
NRC	Nuclear Regulatory Commission
NRSC	National Radiation Safety Committee
PVAMC	VA Medical Center Philadelphia
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
Sv	Sievert
TRUS	trans-rectal ultrasound

Attachment